UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,103	04/07/2008	Pascal Paganon	148821-110229	1061
	7590 04/16/201 <sup>.</sup> IORNBURG LLP	EXAMINER		
Suite 1150	Dood N.E.	GRAHAM, BRIAN J		
3343 Peachtree Atlanta, GA 303			ART UNIT	PAPER NUMBER
			3734	
			NOTIFICATION DATE	DELIVERY MODE
			04/16/2010	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent-at@btlaw.com

		Application No.	Applicant(s)			
Office Action Summary		10/598,103	PAGANON ET AL.			
		Examiner	Art Unit			
		BRIAN GRAHAM	3734			
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) 又	Responsive to communication(s) filed on <u>07 Ja</u>	nuary 2010				
·	This action is <b>FINAL</b> . 2b) ☐ This action is non-final.					
3)□	· <del></del>					
٥)ا	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
	closed in accordance with the practice under z	x parte Quayle, 1900 C.D. 11, 40	0.0.210.			
Disposit	ion of Claims					
4)🛛	Claim(s) <u>1-24</u> is/are pending in the application.					
	4a) Of the above claim(s) is/are withdrawn from consideration.					
5)	5) Claim(s) is/are allowed.					
6)🖂	6)⊠ Claim(s) <u>1-24</u> is/are rejected.					
7)	Claim(s) is/are objected to.					
8)	Claim(s) are subject to restriction and/or	election requirement.				
Application Papers						
9)□	The specification is objected to by the Examine	r				
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
.0,						
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
	under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ul>						
	See the attached detailed Office action for a list of the straight of the stra	of the certified copies not receive	d.			
Attachment(s)  1) \[ \sum \text{Notice of References Cited (PTO-892)} \]  4) \[ \sum \text{Interview Summary (PTO-413)} \]						
2) Notice (3) Information	te of References Cited (FTO-692) te of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) or No(s)/Mail Date	Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	te			

Application/Control Number: 10/598,103

Art Unit: 3734

#### **DETAILED ACTION**

This action is responsive to the amendment filed January 7, 2010.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-8, 11, 16-17, 19, 21, and 23-24 are rejected under 35
U.S.C. 102(b) as being anticipated by Lai *et al.*, hereinafter referenced as "Lai" (United States Patent Number 4,739,758).

Lai discloses an expandable intragastric balloon (10) comprising an outer casing (21) and an inflation chamber (22) within the casing, both of which are flexible enough to pass from a reduced-volume shape into the stomach of a patient (see Figure 6).

Regarding claims 6-8, Lai discloses the inflation chamber is made of a low gas permeable EVA (col. 3, lines 41-54).

Regarding claim 11, Lai discloses coating the outer casing with silicone rubber to provide additional bio-compatibility (col. 1, lines 60-68).

Regarding claim 23. Lai discloses an balloon as claimed comprising an outer casing (10) and an inner pouch (22).

Regarding claim 24, Lai discloses a valve as claimed (25).

Deleted: Graham, provide an introductory status on the status of the amendment: i.e.¶ - - This action is responsive to .... - - (see previous comments sent to you.)¶ This action is a second non-final, yet you said the arguments were not persuasive. So why not a Final In the Search Notes; when a limited class/sub search is done, place in "search notes" box. See MPEP 704+¶ GRAHAM, this is the last time I'll make this request of you, since is merely a formality and does not affect the substance of the know the protocol. Now it will be

between you and SPE whether or not you provide the introduction

statement in the future T However, you must make the correct changes in the search notes according to the MPEP as I

Page 2

Formatted: Left

ha indicated. ¶ Thanks¶

Formatted: Highlight

Deleted: ¶

Formatted: Font: 10 pt

Formatted: Font: Not Bold

Application/Control Number: 10/598,103

Art Unit: 3734

### Claim Rejections - 35 USC § 103

Page 3

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5, 12-14, and 22 are rejected under 35 U.S.C. 103 as being unpatentable over Lai in view of Gau *et al.*, hereinafter referenced as "Gau" (United States Patent Number 5,084,061).

While Lai fails to disclose an elastomer material, Gau discloses an intragastric balloon which is made of the elastomer silicone (elastomeric shell 22). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inflation chamber and/or shield of Lai with the elastomeric material of Gau in order to provide flexibility while retaining low gas permeability.

Claims 9-10 are rejected under 35 U.S.C. 103 as being unpatentable over Lai in view of Garren *et al.*, hereinafter referenced as "Garren" (United States Patent Number 4,899,747).

While Lai fails to disclose the shield of inner pouch being made of polyurethane, Garren discloses an intragastric balloon wherein the combined inflation pouch and shield are made of polyurethane (col. 3, lines 30-51). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inflation

Application/Control Number: 10/598,103

Art Unit: 3734

chamber and/or shield of Lai with the polyurethane material of Garren in order to provide flexibility while retaining low gas permeability.

Page 4

Claims 15, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai in view of Paganon (United States Patent Application Publication Number 2007/0135829).

While Lai fails to disclose the inflation chamber and the outer layer being movable relative to each other, Paganon discloses an intragastric bag apparatus which utilizes an inflation chamber (10) separate from the outer layer (8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the separate chamber construction of Paganon in the balloon of Lai in order to provide a means of alternating the balloon between two varying inflated states.

Paganon further discloses coating the balloon in parylene (abstract).

## Response to Arguments

Applicant's arguments filed January 7, 2010 have been fully considered but they are not persuasive.

Applicant argues that the outer pouch of Lai is bonded to the balloon and as such does not constitute a substantially separate and independent means for forming the outer casing. Examiner disagrees. As quoted by Applicant in the reply filed January 7, 2010, Lai discloses that the outer silicone layer "may be bonded to the outer surface of the balloon." The language "may be" indicates that the bonding of the silicone to the

balloon is not a mandatory component of the invention, and that the silicone may also NOT be bonded to the balloon, yielding a substantially separate and independent means for forming the outer casing.

#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN GRAHAM whose telephone number is (571)270-7484. The examiner can normally be reached on Monday - Friday 8:00 am-5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/598,103 Page 6

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B.J.G./ April 1, 2010

/Todd E Manahan/ Supervisory Patent Examiner, Art Unit 3734